REMARKS

Status of the Claims

The pending Office Action addresses claims 1-77. Examiner states claims 1-36, 40-67 and 69-77 were withdrawn, and claims 37-40 and 68 stand rejected. Claims 1-6, 18, 21-35, 41-49, 52-58, and 63-77 are canceled. Claims 7-17, 19, 20, 36, 37, 50, 51, and 59-62 are amended, and new claim 78 is herein added. Reconsideration and allowance are requested.

Amendments to the Drawings

Applicant submits formal drawings attached hereto as "Replacement Sheets." Applicant respectfully requests that the drawings now be accepted.

Amendments to the Specification

The Examiner has objected to the translation of the specification, requiring that a substitute specification be filed in "proper idiomatic English." The Examiner also objects to the Abstract because it exceeds 150 words.

A replacement specification pursuant to 37 CFR § 1.125 is submitted herewith. The replacement specification includes no new matter.

Double Patenting

The Examiner has provisionally rejected claims 37-40 as claiming the same invention as claims 53-56 of copending Application No. 10/947,496. Applicant notes first, that the double patenting rejection is provisional, and second, that independent claim 37 is amended herein. Applicant expects that the double patenting issues will be resolved during prosecution.

Applicant also wishes to direct the Examiner's attention to two additional co-pending, commonly assigned patent applications. In particular, application no. 11/847,488 includes a claim 37 that is copied from claim 37 in this application (in fact, that application includes a substantial number of claims that copied from this application), as well as application no. 10/405,113, which contains no copied claims but which the Examiner may want to consider for double patenting or other purposes.

Rejections Pursuant to 35 U.S.C. § 102(b)

The Examiner rejects claims 37-40 pursuant to 35 U.S.C. § 102(b) as being anticipated by U.S. Patent No. 4,250,887 (Dardik). Specifically, The Examiner states:

> Dardik et al. teaches:
>
> a. Concerning claim 37: a method for delivering a viscous material under a radiation field 14 and capable of delivering a viscous material (col. 3, I. 64) under fluoroscopy (naturally follows from x-ray field 14 which in the sense of desirability of reducing exposure to radiation is functionally equivalent) to a site in a patient comprising the steps of: a) providing a delivery tube containing an incompressible fluid and a viscous material, wherein the viscous material is located within the radiation field, in which a fluoroscopy field would be functionally equivalent (col. 4, II. 51-53; 24 pumps material through 27 which is seen in the x-ray field in Fig. 1); and b) pressurizing the incompressible fluid outside the radiation field, in which a fluoroscopy field would be functionally equivalent, to exert pressure on the viscous material (Fig. 1; col. 2, I. 61 to col. 3, I. 15).
>
> b. Concerning claims 38-40: the delivery tube 33 is flexible and noncompliant (col. 4, II. 15-20); a linear actuator 22 is involved; determining the amount delivered can be made from a visualization window 20 (col. 5, II. 3-7).

Applicants have amended independent claim 37 to include the viscous bone cement recitation from claim 68, which is not subject to this rejection. Additionally, new independent claim 78 also includes the viscous bone cement recitation. Accordingly, Applicants believe that this rejection is obviated.

Rejections Pursuant to 35 U.S.C. § 103(a)

The Rejection

The Examiner rejects claims 37 and 68 pursuant to 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 6,676,664 (Al-Assir) in view of Dardik. Specifically, the Examiner states:

Al-Assir teaches a method for delivering a viscous material, namely bone cement, under a radiation field (col. 2, II. 5-8) and capable of delivering a viscous material, namely bone cement (col. 5, II. 13-15), under fluoroscopy (naturally follows from x-ray field, which in the sense of desirability of reducing exposure to radiation is functionally equivalent), which includes the viscous material in the radiation field, but includes pressurizing the viscous material using mechanical means rather then hydraulic means.

Dardik et al. teaches a method for delivering a viscous material (col. 3, I. 64) under a radiation field 14 and capable of delivering a viscous material, namely bone cement (naturally follows from similar structure to applicant), under fluoroscopy (naturally follows from x-ray field 14 which in the sense of desirability of reducing exposure to radiation is functionally equivalent) to a site in a patient comprising the steps of: a) providing a delivery tube containing an incompressible fluid and a viscous material, wherein the viscous material is located within the radiation field, in which a fluoroscopy field would be functionally equivalent (col. 4, II. 51-53; 24 pumps material through 27 which is seen in the x-ray field in Fig. 1); and b) pressurizing the incompressible fluid outside the radiation field, in which a fluoroscopy field would be functionally equivalent, to exert pressure on the viscous material (Fig. 1; col. 2, I. 61 to col. 3, I. 15). Dardik et al. teaches this method in order to reduce the radiation exposure to the surgeon (Abstract).

It would have been obvious to someone of ordinary skill in the art at the time of the invention to substitute the steps and apparatus of Dardik et al. into the method of Al-Assir because the substitution would have yielded predictable results, namely to reduce the radiation exposure of the surgeon.

Background and Review of the References Cited

Dardik provides a system for the remote dispensing of angiographic dye, while maintaining surgeon "feel" while dispensing:

> The present invention provides a system whereby a surgeon can manually, ***with conventional force and feel,*** cause injection of a radiopaque dye during angiography . . . [Col. 2, lines 52-54.]

Dardik further states that in a "preferred embodiment" (in fact, it is the only embodiment, and thus the only disclosure on this topic in Dardik), Dardik uses as his driving fluid:

> a fluid such as water or oil, which might have a ***density and viscosity generally similar to that of the radiopaque injectate.*** [Col. 2, lines 63 to 65]

There are three results from constructing the angeographic dye injector in the manner described by Dardick: (1) the surgeon maintains the "feel" of injecting the dye, even at a distance; (2) the dye is injected at the same rate that the surgeon works the remote plunger; and (3) the device can be made from standard tubing and syringes:

> With an apparatus as described above, ***the drive syringe and plunger are not only visually familiar to the surgeon, but they are and feel identical to the conventional injectate syringe.*** Modifications may be made if necessary in the dimensions of the drive and driven syringes and intermediate hose filled with fluid, to be sure they ***simulate closely the feel of direct manual injection*** of radiopaque dye, in regard to the mass and viscosity of the dye and the force to discharge same. [Col. 3, lines 16-24.] . . . From this position the surgeon can observe both the area of vascular reconstruction and the coupled syringes; at the same time he has the ***personal control by virtue of the familiar, manual "feel" of the syringe and plunger, of the fluid flow and/or resistance to the flow.*** [Col. 5, lines 3 to 8.]

* * *

> ***[T]he driven plunger***, when moved axially, ***will drive the injectate plunger essentially the same distance and at the same rate*** in an ideal hydraulic system. [Col. 3, lines 11-14.]

* * *

> Not only does this new invention provide an apparatus that allows "manual" injection from a remote and radiation-safe location, it is extremely simple to use and inexpensive to manufacture; ***even standard syringes and tubing can be used*** . . . [Col. 3, lines 25-30.]

The system of Dardik will not work with a viscous bone cement. The Al-Assir paper cited by the Examiner ("Percutaneous Vertebroplasty: A Special Syringe for Cement Injection," 21 Am. J. Neuroradiol. 159-161 (Jan. 2000)) puts this most directly in its Summary:

> Summary: Percutaneous vertebroplasty is an effective treatment for many focal vertebral lesions. Methyl

> methacrylate is too viscous to be handled without difficulty in the conventional way because injection time is short. The operator is left with little time and must fumble with multiple syringes. We describe a special screw-system syringe that decreases the effort needed to inject the cement. In addition, it can standardize the injection pressures and control the injected volume because the threaded plunger affords greater control of injection pressure and volume delivered than does the conventional method.

The Al-Assir patent cited by the Examiner in the rejection echoes this theme, noting that "[t]he injection of cementing biomaterials is customarily carried out conventionally with standard syringes . . ." but, "the force to be applied to the plunger needs to be considerable." In other words, the hydraulic fluid delivery system of Dardik, which uses a hydraulic driver in which the driving fluid is similar in viscosity to the delivered fluid, that employs conventional syringes does not work well with bone cement. Al-Assir thus sets out to "improve the methods for injecting hardenable masses in vertebroplastia by facilitating the loading of the biomaterial into the interior of an injector device having special features, making it possible to work with greater injection pressure and to obtain a greater capacity of adjustment thereof . . ." Al-Assir's goal is not to improve upon Dardik, but to replace it entirely with a system that handles higher pressures and larger volumes.

U.S. 6,383,190 to Preissman, also of record in this case, makes this point even more strongly, noting the desirability of high viscosity cements and the many problems involved with injecting them through conventional syringes:

> A viscous or paste-like consistency of PMMA is generally believed to be most advantageous for performing percutaneous vertebroplasty. Such a consistency insures that the implant material stays in place much better than a less viscous, more liquid material. Leakage or seepage of PMMA from the vertebral implant site can cause a host of complications some of which can be very serious and even result in death. For example, Weil et al. reported cases of sciatica and difficulty in swallowing which were related to focal cement leakage, Radiology 1996; Vol 199, No. 1, 241-247. A leak toward the distal veins poses an even more serious risk, since this can cause a pulmonary embolism which is often fatal.

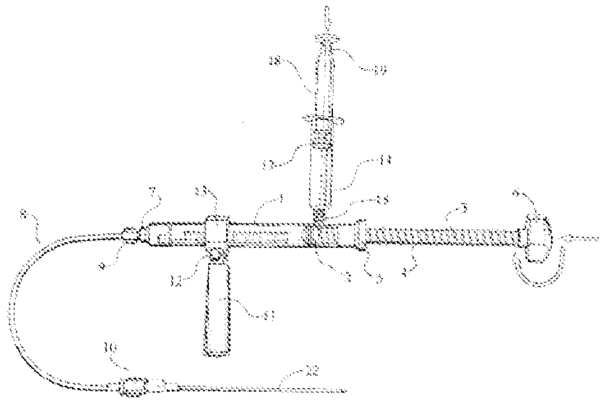
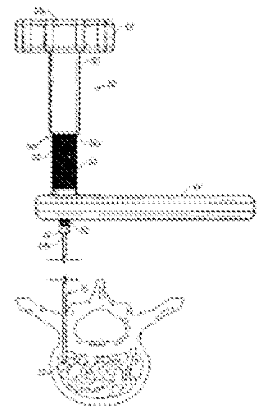
* * *

> Because in general, 10 cc syringes are only capable of generating pressures of about 100-150 psi, this places a limitation on the viscosity of the PMMA that can be effectively "pushed through" the syringe and cannula and fully delivered to the implant site. Of course, the use of a small barrel syringe, e.g., a 1 cc syringe, enables the user to generate higher driving pressures. For example, pressures of 1000 psi and possibly as high as 1200-1500 psi (depending upon the strength of the user and the technique) may be generated using a 1 cc syringe. A serious limitation with the use of a 1 cc syringe, however, is that it will not hold a large enough volume to complete the procedure in one step or "load" and must be reloaded several times to complete the procedure, since, on average, about 3.5 cc of implant material per side of the vertebral body are required for an implantation procedure. This makes the procedure more complicated with more steps, and more risky in that the polymerization of the implant material causes it to become increasingly more viscous during the additional time required for reloading. Another problem with a 1 cc syringe is lack of control, as high pressures are generated in a "spike-like" response time and are not continuously controllable.

* * *

> Thus, there is a need for a high pressure applicator that has enough storage capacity to perform a complete implantation procedure without having to reload the device in the midst of the procedure, and which is consistently controllable, for an even, constant application of pressure during delivery of the entirety of the implant material. [Col. 1, line 63 to col. 2, line 48.]

Not surprisingly, Al-Assir and Preissman both address these problems with devices that are completely different from, and incompatible with, Dardik:

 *Al-Assir*	 *Preissman*

Both Al-Assir and Preissman provide direct, mechanically-advantaged of bone cement through an elongated tube and/or needle. According to both, this is how one injects viscous bone cement – not using the standard syringes of Dardik.

Response to Obviousness Rejection

The rejection of bone-cement claim 68 (now, all of the claims recite bone cement) begins with Al-Assir as the primary reference. According to the rejection, Al-Assir delivers a viscous bone cement under a radiation field – and that it would have been obvious to someone of ordinary skill in the art at the time of the invention to substitute the steps and apparatus of Dardik et al. into the method of Al-Assir because the substitution would have yielded predictable results, namely to reduce exposure of the surgeon.

First, the purported obviousness rationale (and the description of Al-Assir), does not square with the references. Al-Assir does acknowledge the use of x-ray imaging during delivery of bone cement – but Al-Assir specifically addresses the issue of reducing exposure of the surgeon to the X-rays:

A. Puncture and Access:

* * *

The ***use of the long stylet also makes it possible to keep the operator's hands away from the area subjected to ionizing rays (X-rays)***, if this technology is used during

> the procedure. In these circumstances, the irradiation which the hands may receive during the manipulation of the puncture equipment is reduced.
>
> B. Use of the High Pressure Flexible Tube:
>
> ***This makes it possible to keep the operator's hands away from the irradiated area.*** Moreover, the movements of the operator's hands are not transmitted to the needle, so that accidental displacements of the latter are avoided. [Col. 3, lines 14-34.]
>
> * * *
>
> Moreover, owing to the arrangement of the tubular member capable of functioning at high pressure, ***the surgeon's hands can remain substantially separated from the direct site of the intervention, thus avoiding excessive exposure to the radiation of the X-ray apparatus*** used for locating the site of the operation. [Col.5, lines 16-21.]

Al-Assir already addresses the issue of reducing the radiation exposure to the surgeon, and does so in a different way than Dardik – in particular, Al-Assir uses the length of the high pressure tubing and stylet to move the move the surgeon away from the ionizing radiation.

The rationale for modifying Al-Assir stated in the rejection is thus a nullity as the rationale is directly contrary to Al-Assir. In order to make out an obvious rejection, the Examiner must provide clear reasons why the person of ordinary skill would make the leap from the prior art to the claims. *See In re Kahn*, 441 F.3d 977, 988 (CA Fed. 2006) ("[R]ejections on obviousness grounds cannot be sustained by mere conclusory statements; instead, there ***must be some articulated reasoning with some rational underpinning*** to support the legal conclusion of obviousness") (emphasis added). Without such rational underpinning, the Examiner easily fall prey to improper hindsight reasoning:

> A factfinder should be aware, of course, of the distortion caused by hindsight bias and must be cautious of arguments reliant upon *ex post* reasoning. *See Graham*, 383 U.S., at 36, 86 S. Ct. 684, 15 L. Ed. 2d 545 (warning against a "temptation to read into the prior art the teachings of the invention in issue" and instructing courts to "'guard against slipping into the use of hindsight'".) *KSR Int'l Co. v. Teleflex Inc.*, 127 S.Ct. 1727, 1742 (Apr. 30, 2007).

Here, where the rational underpinning for the obviousness conclusion fails when compared to the reference, there is in fact no rational underpinning for the combination and a proper obviousness rejection cannot be maintained.

In addition, Al-Assir expressly says that conventional syringes such as those used by Dardik (and Dardik believes that it is an advantage to use them) will not work with viscous bone cement (as explained in detail above). Modifying Al-Assir by adding the proposed features of Dardik would expressly render Al-Assir incapable of performing its stated purpose of delivering viscous bone cement. According to MPEP § 2143.01(V), "[i]f [the] proposed modification would render the prior art invention being modified unsatisfactory for its intended purpose, then there is no suggestion or motivation to make the propose modification" (citation omitted). Further, in accordance with MPEP § 2143.01(VI), "[i]f the proposed modification or combination of the prior art would change the principle of operation of the prior art invention being modified, then the teachings of the references are not sufficient to render the claims prima facie obvious" (citation omitted). For this additional reason, the obviousness rejection should not be maintained.

CONCLUSION

The pending claims are in condition for allowance. Applicants request that the Examiner telephone the undersigned in the event that such communication is deemed to expedite prosecution of this matter.

In the event that a petition for an extension of time is required to be submitted at this time, Applicant hereby petitions under 37 CFR 1.136(a) for an extension of time for as many months as are required to ensure that the above-identified application does not become abandoned.

The Director is hereby authorized to charge any deficiency in the fees filed, asserted to be filed or which should have been filed herewith (or with any paper hereafter filed in this application by this firm) to our Deposit Account No. 141449, under Order No. 101896-890.

Respectfully submitted,

Date: July 21, 2008

Ronald E. Cahill
Reg. No. 38,403
Attorney for Applicant

NUTTER, McCLENNEN & FISH, LLP
World Trade Center West
155 Seaport Boulevard
Boston, MA 02110
Tel: (617) 439-2782
Fax: (617) 310-9782

APPENDIX I
MARKED-UP COPY OF REPLACEMENT SPECIFICATION

HYDRAULIC DEVICE FOR INJECTION OF BONE CEMENT IN PERCUTANEOUS VERTEBROPLASTY

CROSS-REFERENCE TO RELATED APPLICATIONS

[0001] This application is the National Phase Application of International Application No. PCT/MX2003/000027 filed March 14, 2003.

TECHNICAL FIELD

[0002] This invention ~~in a general way~~ relates generally to ~~the~~ medical ~~area in~~ procedures where it is required to inject a dense or viscous fluid through a needle, in a particular way the viscous material is ~~the~~ polymethylmethacrylate. It is used in procedures like percutaneous vertebroplasty, kyphoplasty or other surgical events of the field. It has applications in other areas where it is required to apply at distance a dense and viscous liquid.

BACKGROUND OF THE INVENTION

[0003] Percutaneous vertebroplasty is a minimally invasive interventional radiological procedure that consists ~~on~~ of injecting bone cement (Polymethylrnethacrylate, PMMA) in the vertebral body[[,]] by trans-pedicular or oblique approach through a bone biopsy needle.

[0004] It was developed in France in 1984 for the treatment of aggressive or painful degenerative conditions ~~haemangiomas~~ of vertebral bodies. For its analgesic effect, its use was quickly extended for the treatment of ~~lytic~~ metastatic lesions or myeloma and mainly in fractures or vertebral collapse due to osteoporosis. The procedure is indicated in those cases that are presented with severe and disabling pain that doesn't respond to conservative measures such as: corset use, analgesic and anti-inflammatory treatment or bed rest.

[0005] Most of the patients with this suffering are between the 6th and 8th decade of life. In this group of advanced age, the immobilization resulting from vertebral fractures has severe

consequences in their general medical conditions, it predisposes them to cardiopulmonary, intestinal, circulatory complications, etc. Besides pain, the psychological effects can be devastating, it deteriorates the quality and reduces the expectation of life.

[0006] Vertebroplasty is a procedure that is carried out in hospital facilities that requires specialized medical personnel. It is performed in a ~~hemodinamia room or~~ cath lab, and it requires of the use of radiological equipment with high resolution fluoroscopy, mounted in a C arm. Currently, this injection is carried out in a manual and direct way and the operator is exposed to ionizing radiation every time that he/she practices a vertebroplasty. The injection of bone cement is made with fluoroscopic control, connecting an insulin syringe to the needle. This implies that the surgeon is in direct contact with the patient and therefore, overexposed to primary or secondary ionizing radiation during the lapse of the procedure of the vertebroplasty.

[0007] The primary radiation is the X ray beam coming from the X ray tube and received by the patient in a direct way[[,]]. The secondary radiation it the one resulting on the deviation of the primary beam in the patient's body tissues and doesn't contribute to the formation of a diagnostic image, it is spread in all directions and it is the main source of exposure of medical personnel.

[0008] ~~The~~ An insulin syringe is typically used since a small diameter barrel is required to have less resistance for the manual injection of high viscosity bone cement[[,]]. Each ~~each~~ syringe is filled approximately in half or two thirds of its capacity to avoid bending or breaking the plunger when exercising the required injecting pressure that may be considerable. The volume needed to obtain the expected results varies from 3 ml up to 9 ml, therefore, 5 to 18 syringe exchanges are necessary, this favors the solidification of the polymethylmethacrylate and it can prevent to inject the wanted quantity.

[0009] If larger diameter syringes are used, ~~the~~ manual pressure is insufficient due to the density and viscosity of the bone cement[[;]] and becomes necessary ~~the employment of~~ to employ a mechanical device to be able to exercise the required pressure. At ~~the state of the art~~ present, there are commercially[[.]] available devices such as pressure gun type or threaded plunger mechanisms connected directly to the needle that ~~deposits~~ deposit the cement in the bone

or through a high pressure short tube. The use of a long tube would have considerable resistance to the flow of the cement, favoring its solidification.

[0010] In most of these devices the syringe is not interchangeable, it is loaded with the total volume to inject and therefore, ~~are of~~ has a larger diameter, and ~~the~~ increased resistance to the flow of the cement becomes worse with time due to solidification of cement.

[0011] On the other hand, ~~the~~ conventional hypodermic syringes are not designed for high pressure injection, the plunger and the fingers supporting wings bend easily.

[0012] The devices of the previous technique solve only the mechanical problem of injecting the dense and viscous cement through the needle, but they are focused on exercising the necessary pressure directly on the patient or at a very short distance of the radiation source. They don't allow the operator to maintain an appropriate distance to reduced exposure to secondary radiation at acceptable levels according with the international radiological protection norms.

[0013] On the other hand, some mechanical devices do not allow control or manual sensibility of the exercised pressure and speed of the injection of the cement, important factors in the prevention of undesirable leaks and complications. Some devices that apply cement in the current state of the art are for example:

[0014] ~~The patent application of the~~ United States Patent Publication No. ~~of America~~ 2003/0018339, ~~for~~ to Higueras et al, published January 23th of 2003, ~~it~~ discloses ~~an application~~ a device for the controlled injection of bone cement, mounted in a syringe loaded with the cement[[,]] as a cartridge, which is discharged by a threaded metallic plunger placed in the other end of the device[[,]]. ~~it~~ The device is useful for controlling the pressure exercised on the plunger of the syringe, but it is a short device in which the operator is near the patient[[;]]. It also contains the total load of cement.

[0015] On the other hand, due to the quantity and viscosity of the cement~~, and quantity keeps certain~~ it has a dynamic memory that doesn't allow sudden interruption of the injection.

[0016] ~~The patent application of the~~ United States Patent Publication ~~of America~~ No. 2002/0156483, ~~for~~ to Voellmicke et al, published October 24th of 2002, discloses a vertebroplasty device ~~and bone cement, it contains~~ having two compartments, one for mixture of the cement and the other for storage and injection into the bone. This dual ~~camera~~ chamber device for blending and injection[[,]] consists of a ~~lodging camera~~ delivery chamber with a plunger moving ~~in an axial way,~~ axially. ~~the cameras~~ The chambers are in communication ~~by~~ through a check valve that only allows the passage of the cement in one direction. An extra force can be ~~exercise~~ exercised on the plunger by means of a lever that increases the mechanical force and therefore the pressure in the injection ~~camera~~ chamber. This is a device in which it is necessary to work the piston of the blending ~~camera~~ chamber and the piston of the injection ~~camera~~ chamber to empty one and fill the other one alternatively. It is a short device, with the result that it is necessary to be near the patient and doesn't reduce the exposure to secondary ionizing radiation.

[0017] ~~The patent application of the~~ United States Patent Publication ~~of America~~ No. 2002/0099384, ~~for~~ to Scribner et al, published July 25th of 2002, discloses a system and method to treat vertebral bodies. It is a special syringe with two concentric plungers. The first ~~camera that~~ chamber has a first transverse section and a second ~~smaller camera~~ chamber is smaller than the first one. Both ~~cameras~~ chambers communicate ~~to~~ with each other. The first ~~camera~~ chamber includes a gate to receive the material inside the filling instrument, the second ~~camera~~ chamber includes a gate to discharge the contained material. A first plunger suited to pass through the first ~~camera~~ chamber and displace the material. A second plunger to pass through the interior of the first plunger's concentric hole and reach the interior of the second ~~camera~~ chamber to displace the material through the exit in the second camera to inject into the needle toward the interior of the vertebral body. Although this device provides control in the injection of the bone cement, the operator is too near the patient.

[0018] In general, the injection devices have a bolster that impels the viscous fluid by means of a manual trigger moved by a screw mechanism (inclined plane), there are others that have a gun like body such as the device of the Patent Application of the United States Patent Publication No. ~~of America.~~ 2002/0049448, ~~for~~ to Sand et al, published April 25th, 2002[[,]]. It

has a tubular body that stores a viscous flowing material (bone cement)[[,]]. ~~it~~ The body is a longitudinal body with a providing end and a driving end, a plunger housed inside the tubular body that displaces the flowing material along the longitudinal axis of the tubular body, and a ~~the~~ driving mechanism that has a handle like a gun to hold with a hand, while injecting with the other hand by means of the plunger that advances due the pressure exerted by a threaded mechanism. These mechanisms with big deposits have the inconvenience that the cement can end up solidifying in the conduit at the time of application and impede to apply the total amount of cement inside the affected vertebral body. On the other hand, with the excess of pressure generated by these devices, the cement could leak outside of the vertebral body, since the fluid (PMMA), for its viscosity, possesses a remaining flowing memory that may be difficult to control.

[0019] ~~The Patent of the~~ United States Patent No. ~~of America Not.~~ 6,348,055, ~~for~~ to Preissman, published February 19th of 2002, ~~protects~~ provides a bone cement applying device with screw mechanism in which the preparation of the total volume of cement is made[[,]]. ~~this~~ This mechanism has an intermediate stabilizer that avoids the ~~turns of~~ need to turn the whole device during the application of pressure to the fluid. The stabilizer is a lever perpendicular to the screw body that can be ~~sustain~~ sustained with [[a]] one hand, while with the other hand exercises the pressure to inject the cement inside the vertebral body. This device is also operated very near the patient and therefore, the operator is exposed to secondary ionizing radiation. Another inconvenience is that if the cement "solidifies in the system and has not reached the vertebral body in the proper amount, it is necessary to make another preparation ~~previous placement~~ of another needle in a different and appropriate position for the new requirement.

[0020] ~~The Patent Application of the~~ United States Patent Publication ~~of America~~ No. 2002/0010431, ~~for~~ to Dixon et al, published January 24th, 2002, discloses a screw device for high pressure injection with a threaded axis that impels a plunger inside a ~~camera full~~ chamber filled with viscous bone cement. This device has the ~~inconvenience~~ inconveniences that one doesn't have manual sensitivity and control of the pressure exercised[[,]] and it is not easy to exchange the syringes with the bone cement. As a matter of fact, it is the only syringe of the cartridge.

BRIEF SUMMARY OF THE INVENTION

[0021] Among the several objects of the present invention, a better control of the pressure in the placement of bone cement or other viscous materials in the bone is provided. The invention facilitates the injection of viscous filler in trabecular bone or a cavity formed in the vertebral body.

[0022] Another object of the present invention it is to provide a hydraulic device to treat vertebral fractures and reduce the pain, stabilize the vertebral body, ~~to~~ obtain higher resistance to compression, and avoid further collapse and at the same time[[,]] to allow early mobilization of the patients and improve their quality of life.

[0023] It is still another object of the present invention[[,]] to provide a device for the injection of viscous material in the vertebral body that allows the operator to keep and appropriate distance (1.0 m to 1.5 m) in order to reduce exposure to ionizing radiation at acceptable levels within the international norms.

[0024] It is also another object of the present invention, to provide a hydraulic press like device using syringes of unequal caliber (3 and 10 ml) to exercise hydraulic pressure at distance transmitted from a proximal, manual syringe of smaller caliber, through the polyethylene tube until the distal or injecting syringe.

[0025] It is another object of the present invention to provide a pressure cylinder ~~of pressure~~ with mechanical advantage complementary to ~~an~~ a hydraulic system of syringes for injection at distance of a polymethylmethacrylate ~~suspension~~ cement in the cancellous bone of a vertebral body. This way, the overexposure of the operator to ionizing radiation is reduced.

[0026] It is still another object of the present invention to provide a hollow cylinder or pressure body ~~of pressure~~ in the shape of an inverted syringe to form a hydraulic device that allows manual control on the volume and velocity of injection polymethylmethacrylate (PMMA) and also immediate interruption of the pressure applied on the fluid.

[0027] It is still ~~an~~ another object of the present invention, to provide a device that prevents the movements or abnormal displacements of the needle during the injection and syringes exchange (1 or 2 exchanges may be necessary), ~~it~~ to reduce ~~reduces~~ time loss and ~~allows~~ allow to maintain the bone cement loaded syringes in a recipient or cold atmosphere to slow time of solidification.

[0028] It is another object of the present invention[[,]] to provide a device that uses syringes from 3 to 5 ml that require smaller injection pressure, and can be exchanged easily with a single 90° rotation movement~~, Hub Lock type~~ of a hub lock.

[0029] It is still ~~an~~ another object of the present invention[[,]] to provide a device for injection of viscous material that can be manufactured of plastic, aluminum or any other disposable light-weighted material for single use or suitable for re-sterilization, sturdy enough to support the pressure of injection.[[.]]

[0030] It is another object of the present invention to provide a flexible hydraulic, ~~light-weighted~~ light-weight device that prevents the movements or unwanted displacements of the needle during the injection.

BRIEF DESCRIPTION OF THE DRAWINGS

[0031] ~~The figure~~ Figure 1[[,]] represents the connection outline of ~~the novel~~ a hydraulic press ~~like~~ injection device ~~for injection at distance,~~ of the present invention[[.]];

[0032] ~~The figure~~ Figure 2[[,]] represents an injection device with a screw type threaded plunger of the previous technique[[.]];

[0033] ~~The figure~~ Figure 3[[,]] represents [[a]] an injection device ~~of injection~~ of the previous technique, which has a ~~recipient~~ chamber to make the mixture, another to exercise the injecting pressure[[.]] wherein each ~~recipient~~ chamber contains a check valve in their exit holes to avoid re-flow;

[0034] ~~The figure~~ Figure 4[[,]] represents [[a]] an injection device ~~of injection~~ of the previous technique, which contains a larger capacity syringe in which the total amount of bone cement mixture is placed to inject[[,]] and impelled by a threaded plunger[[.]];

[0035] ~~The figure~~ Figure 5 represents ~~the~~ a device ~~object~~ of the present invention corresponding to the transverse view of the piston together with the rubber cap[[.]];

[0036] ~~The figure~~ Figure 6 represents ~~the~~ a smaller, manual syringe of the invention for control of the device with the plunger and rubber cap[[.]];

[0037] ~~The figure~~ Figure 7[[,]] ~~it~~ represents ~~the~~ an actuator syringe ~~of force~~, the conduit (7) that transmits the pressure to the larger diameter device (B) [[.]]and the way to place the plunger (A) of the injecting syringe that contains the material and the injection needle[[.]];

[0038] ~~The figure~~ Figure 8[[,]] represents a hydraulic press[[,]] according to the theoretical basic principles of the present invention[[.]]; and

[0039] ~~The figure~~ Figure 9[[,]] represents the pressure transmitted in the tube and the exit force generated, which pushes the plunger that injects the material through the needle.

DETAILED DESCRIPTION OF THE INVENTION

[0040] The present describes a new device and method to treat affections of the bones, specifically, in the treatment of osteoporotic or fractured vertebral bodies.

[0041] These bone structures have different pathological states of diverse ethiology (trauma, osteoporosis, primary bone tumors or metastasys, etc.). An alternative of treatment to stabilize and to consolidate this structures consists on the injection of a bio-materials such as polymethylmethacrylate in the interior of the vertebral body for healing purpose.

[0042] The injection of biomaterials such as bone cement is carried out by means of a hydraulic device exerting pressure on small caliber conventional syringes connected directly to the needle[[;]], since the cement has the property of becoming hard quickly.

[0043] The theoretical basic principle for the operation of the device of the present invention consists on the amplification of the hydraulic pressure generated at distance and transmitted by the hydraulic tube.

[0044] In reference to ~~the figure~~ Figure 8, the most frequent application ~~to~~ of the Law of Pascal is the hydraulic press that consists of two asymmetric columns of liquid. This principle is applied in mechanical devices of engineering areas~~, this~~ where the columns are different in the size or diameter of the transverse section. In accordance with the Law of Pascal, a pressure applied in one of the columns is transmitted entirely and in all directions. Therefore, if a force F_1 is applied on the area piston A_1, it will cause an exit force F_0 that acts on an area A_0 of the piston. This way, the entrance pressure is the same to the exit pressure, that is to say:

$$F_1/A_1 = F_0/A_0$$

[0045] The ideal mechanical advantage of the device is similar to the relationship of the exit force with regard to the entrance force[[.]]:

$$VM = F_0/F_1 = A_0/A_1$$

[0046] Where a small entrance force can be multiplied (A_0/A_1 times) to produce a larger exit force (F_0), using an exit piston with a larger area than that of the entrance piston. The exit force will be given by:

$$F_0 = F_1\ A_0/A_1$$

[0047] If friction is disregarded, in an ideal situation the entrance work should be the same ~~to~~ as the exit work. Therefore, if the force F_1 travels a distance S_1 while the exit force F_0 travels a distance S_0, there is equality[[.]]:

$$F_1S_1 = F_0S_0$$

[0048] The mechanical advantage can be expressed in terms of the distances traveled by the pistons:

$$VM = F_0/F_1 = S_1/S_0$$

[0049] It is observed that the mechanical advantage is obtained at expenses of the distance that the entrance piston travels.

[0050] In reference to ~~the figure~~ Figure 9 that describes the body (B) and area (95) of the piston of larger area of the present invention, ~~it is also represented the entrance of~~ the pressure P_I that is transmitted through the incompressible fluid, either water or oil, ~~content~~ present in the flexible tube (not shown) that generates an exit force F_0. The attachment (2) for the lateral wings of the injecting syringe that contains the bone cement acts as coupler to the device, the wings enter tightly in the internal peripheral groove (70) diametrically opposed inside the bolster(header) of the body of the device object of the present invention, with a turn of 90° either clockwise or counterclockwise. The plunger of the syringe enters in the longitudinal central space (95) of the body (B).

[0051] Returning to ~~the figure~~ Figure 1, the hydraulic device consists of four main parts arranged one after another in such a way that allows to inject at a distance and in a controlled way (regarding the pressure) viscous materials such as polymehylmethacrylate used in percutaneous vertebroplasty for the reestablishment (without surgery) of ~~patient~~ a vertebra with osteoporotic fractures.

[0052] The device here described is designed to inject at distance a polymethylmethacrylate suspension with viscous consistency, directly in the cancellous bone of the vertebral bodies by means of a syringe loaded with the bone cement attached to a bone biopsy needle. The device consists of four main parts, "injecting syringe" in vicinity to the patient, "pressure[["]] exerting body," "hydraulic transmission tube" and "manual syringe". In this, the fingers of the operator exercise the controlled force. This control is carried out by the operator's ~~tact~~ tactile sensitivity. This device ~~conforms~~ provides a hydraulic system for polymethylmethacrylate injection at a variable distance from the patient (usually 1 m to 1.5 m).

[0053] The ~~injection part~~ injecting syringe is a commercially available, disposable 3 ml[[.]] hypodermic syringe that (a) ~~that~~ is placed next to the patient, loaded with the bone cement ~~that~~ and consists of a plunger (11) that pushes the material (CO) to be injected in the vertebral body ~~trough~~ through a bone needle (CA), (not shown). This syringe couples tightly in a revolved

way, by means of the opposed wings of support (b), in a peripheral groove in the internal face of the bolster (2) of the pressure body ~~of pressure~~, it is coupled by means of the opposed [[']]wings (b) used as support for the fingers ~~in an act of usual injection~~ for injection in the usual way.[[,]] ~~these~~ These wings (b) are placed in the entrance guide and rotated, either clockwise or counterclockwise an angle of 90°, to stay in tightly fixed to avoid inadvertent detachment and loss of the pressure. The injection needle is coupled by rotating the threaded distal end (CA) in the usual way of common plastic syringes in order to avoid spillage of the material to be injected due to the high pressure exercised on the plunger (c) and its end (3). For exchange, the empty syringe is detached from the needle, and then from the pressure device by means of a 90° rotation, discarded (2) and replaced with another loaded syringe prepared in advance and stored in a cold environment to delay curing and hardening of the cement. The syringe (a) is of 3 or 5 ml capacity.

[0054] The ~~part of~~ pressure[[,]] exerting body consists of distal inverted syringe body (1) of larger diameter that the syringe at the proximal end of the complete device[[,]]. It has a bolster (2) open to ~~the~~ atmospheric pressure that contains an internal peripheral groove where the opposed supporting wings of the injecting disposable hypodermic syringe are coupled (b) with a turn of 90°. Its interior is open to the atmospheric pressure and receives the plunger of the injecting syringe (c) in a extended position to make contact with the rigid surface of the piston (3)[[,]] The piston moves tightly with respect of the internal wall of the device (1) by means of a rubber cap (4), to maintain a closed hydraulic space (5). The distal pressure is transmitted to the piston through the opening or mouthpiece (6) connected to the flexible tube of polyethylene or similar material (7) by means of the hydraulic fluid (10). The rigid surface of the piston (3) exercises pressure (which has been increased by the device) on the plunger(11) of the injecting syringe. The body (1) is manufactured of transparent plastic, aluminum or any other suitable light-weighted and rigid material. Other characteristics of the body will be described (1) with more detail in ~~the figures~~ Figures 5, 7 and 9.

[0055] The hydraulic tube for pressure transmission (~~the~~ Pascal's Principle), is a tube or flexible hose of polyethylene or similar light weight material ~~of little weight~~, with appropriate diameter to couple in the distant and proximal ends of the syringes[[,]]. ~~the longitude is variable,~~

The length can vary, most commonly ~~of~~ from 1.0 m to 1.50 m[[,]]. ~~it is~~ The tube is also resistant to the internal pressure. The tube is loaded of water, oil or other ~~non-compress~~ incompressible fluid (10) to integrate together with the manual ~~proximal~~ syringe and the body of ~~pressure~~ the closed hydraulic system.

[0056] The manual syringe (8)[[,]] has a smaller diameter than the pressure body ~~of pressure~~ (1) in a 2/1, 3/1 or 4/1 ratio that may vary according to the necessity of each case. According to the hydraulic press described in ~~the figure~~ Figure 8, the ~~longitude~~ length of the manual syringe should be larger than that of the pressure body ~~of pressure~~ (1) with the purpose of containing enough volume to displace the piston the distance required to impel the plunger of the injecting syringe. ~~this~~ This way, the quantity required of bone cement is deposited in the vertebral body[[ ]].

[0057] The device works in the following way: a manual force is exercised on the plunger (9) of the manual syringe (8) in its extended position[[,]]. ~~the~~ The force exercises a pressure that is transmitted through the incompressible fluid (10) ~~content~~ present in the flexible tube and in the ~~camera~~ chamber (5) of the pressure body ~~of pressure~~ (1). This pressure exercises an increased force on the plunger of the injecting syringe, due to the mechanical advantage of the relationship of areas or displacements formerly described. The plunger of the injecting syringe, in turn, ~~exert~~ exerts a force that impels (to) the material or cement to be injected in the patient's vertebral body through the bone biopsy needle. Once the total amount or content of the injecting syringe has been delivered, the plunger of the manual syringe is retracted to generate space inside the pressure body ~~of pressure~~ (1) by retracting the piston to replace the emptied syringe with a loaded new syringe to continue the injection. Up to 10 ml[[.]] of bone cement is required to achieve an suitable filling of the fractured vertebral body, therefore, 3 to 4 syringe exchanges may be necessary.

[0058] The bone needle stays in place during the procedure. ~~that~~ That is to say, the movements or abnormal displacements of the needle during the injection are avoided[[,]]. ~~situation that implies~~ This provides several advantages: ~~For~~ for the patient, since additional punctures are less frequent and for the operator with less problems of solidification of the cement.

[0059] Another advantage of the device is that the transmission of the pressure is immediate, that is to say, doesn't have a dynamic memory by effects of the increasing viscosity due to the solidification in the injection conduit specially with prolonged injections, prone to happen in the injecting devices of the previous technique that are loaded with the complete volume of cement to be placed. On the other hand, the threaded plunger doesn't allow tact sensibility regarding the exercised pressure and therefore favors unwanted leakage of the bone cement due to the dynamic memory of the material.

[0060] To this respect we have devices of the previous technique such as the (20) figure 2 that consists of a threaded plunger (23) that impels the contained cement in the camera (24) and a refilling deposit (22) that in turn feeds the camera by means of a plunger (21); A handle (25) that serves for support to the other hand of the operator to facilitate exercise the intense force so that the cement flows in a short tube (26) and it is injected through the needle (27).

[0061] The device (30) of the previous technique of the figure 3 contains two cameras (35) (32) connected by a valve check in the conduit (37). The bone cement is mixed In the camera (35) and impelled to the injection camera (32) by means of a plunger(36), once in the injection camera the cement is impelled by the piston (38) of a plunger (34) moved by a lever that provides the required force (33), forcing the cement through the opening (31) that in turn contains a valve check that closes in the recharge operation.

[0062] The figure 4 illustrate another device (40) of the previous technique for injection of polyrnethylmethacrylate. In this one the threaded plunger (41) has a crank (42) in the end to facilitate impel the total content of the syringe (45), and supporting elements (43) (44) for the other hand of the operator in the action of injection of the bone cement.

[0063] The figure 5, represents a cut profile and front view the body of pressure (50) that shows the groove of the bolster (2) where the injecting syringe that contains the bone cement is secured. Also presents the front view and profile of the piston (51) and the rubber cap (52) that avoids spillage of the hydraulic fluid in the action of transmission of the pressure. With this body of pressure, object of the present invention, is possible to transmit the pressure at distance and therefore reduces exposure of the operator to secondary ionizing radiation coming from the

patient at the time of placement of the bone cement. This body of pressure complies with the characteristic of being light-weighted, may be disposable or reusable, manufactured of plastic, aluminum or other suitable material able to support sterilization.

[0064] The figure 6, represents frontal and lateral views of the manual or impulsion syringe (60), and plunger (61) where the rubber cap is placed (62) to avoid leakage of the hydraulic fluid. The bone cement should be kept in a cold environment before it is applied so it is maintain fluid to avoid solidification in the needle.

[0065] In the figure 7, the transverse cut of the cylindrical hollow body of pressure is described (B) that houses the plunger (A) of the injecting syringe secured in the peripheral groove (70) of this body of pressure, it is connected to the flexible tube (7) that transmits the hydraulic pressure (10), exercised from the manual or impulsion syringe (C) by means of its plunger (9). Here is illustrated the way the injecting syringe is attached to the body of pressure, Once introduced the plunger (A) in the opening of the body of pressure (B) the syringe is turned 90° in such a way that the body of the syringe is tightly secured to proceed with the injection of the bone cement.

[0066] The use of small diameter syringes in the application of the cement has the advantage of less resistance to flow, so a more viscous cement can be injected to reduce the possibilities of leakage from the vertebral body.

[0067] The experts in the technique expect other embodiments of the invention might exist, that is to say, embodiments of instruments built according to the teachings of the present invention. Because many of the characteristics of the embodiments are similar to those previously described. Peculiar embodiments of the invention have been illustrated and described in those that it will be obvious for those experts in the technique that several modifications or changes can be made without leaving the reach of the present invention. The above-mentioned tries to cover with the added claims so that the changes and modifications fall inside the reach of the present invention.

ABSTRACT

~~The present invention relates to the medical field, in particular relates to the practice of percutaneous vertebroplasty where a pair of syringes in the distal extreme of a lengthened hydraulic device, are united by a camera of intermediate connection of larger diameter (pressure exerting body) or modified inverted syringe tube with a bolster, a hydraulic connecting tube of flexible material that transmits the pressure of the smaller diameter manual or impulsion syringe in the proximal extreme of the device toward the intermediate cylindrical larger diameter camera (pressure exerting body), this camera is in an inverted position with regard to the first syringe (fluid control), this intermediate camera has a moving piston longitudinal to the axis of the cylinder that is controlled with the first syringe (manual) and in cooperation with the atmospheric pressure. The injecting syringe loaded with bone cement is coupled with the bolster of the body of pressure, and to the needle that drives the cement toward the interior of the bone. The intermediate camera (pressure exerting body) together with the hydraulic tube and the manual syringe form a hydraulic press system (F/A = f/a) that allows to increase in a potential way the pressure exerted in the first syringe and to make the injection of polymethylmethacrylate (PMMA) at an approximate distance of 1.0 m to 1.5 m.~~

Devices and methods are disclosed for delivering a viscous bone cement material to a patient. A device includes a container containing a viscous bone cement and having an exit port. An actuator having an actuator vessel including a incompressible fluid is hydraulically coupled to the container. The container can be placed adjacent to a desired injection site in a fluoroscopic imaging field while the actuator can be actuated from a location outside of the fluoroscopic imaging field to hydraulically drive a flow of viscous bone cement through the exit port to the desired injection site.